

Medical devices, from innovation, selection, supply and management and the context with other health products



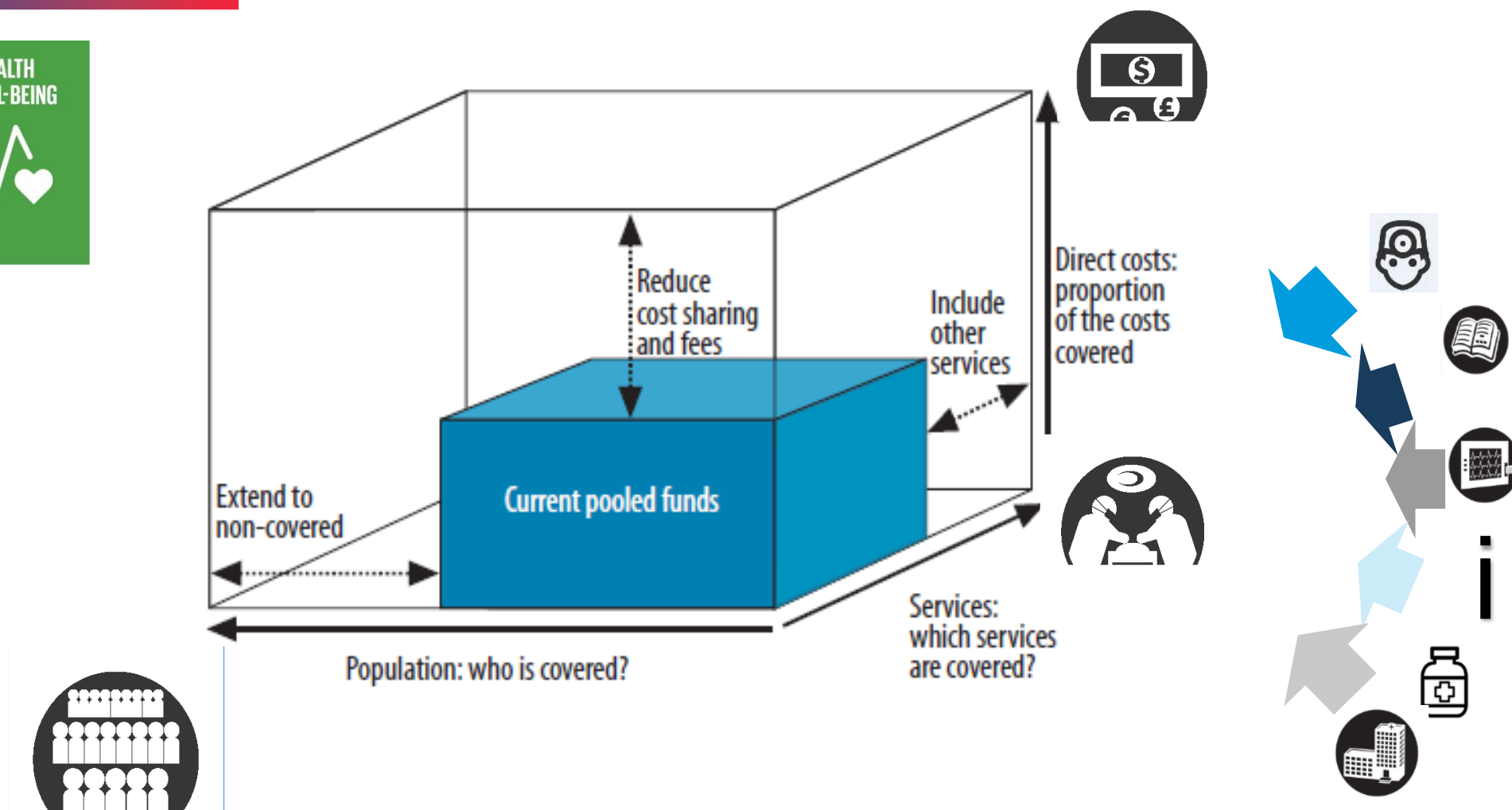
Adriana VELAZQUEZ BERUMEN

Health Products Policy and Standards,
World Health Organization

Goal 3. Good health and well being



SDG3: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services



To ensure improved access of safe, quality medical devices



- » Industry and Academics: Research and development should be based on needs



- » Health Technology Assessment
- » Lists of MD for reimbursement or procurement



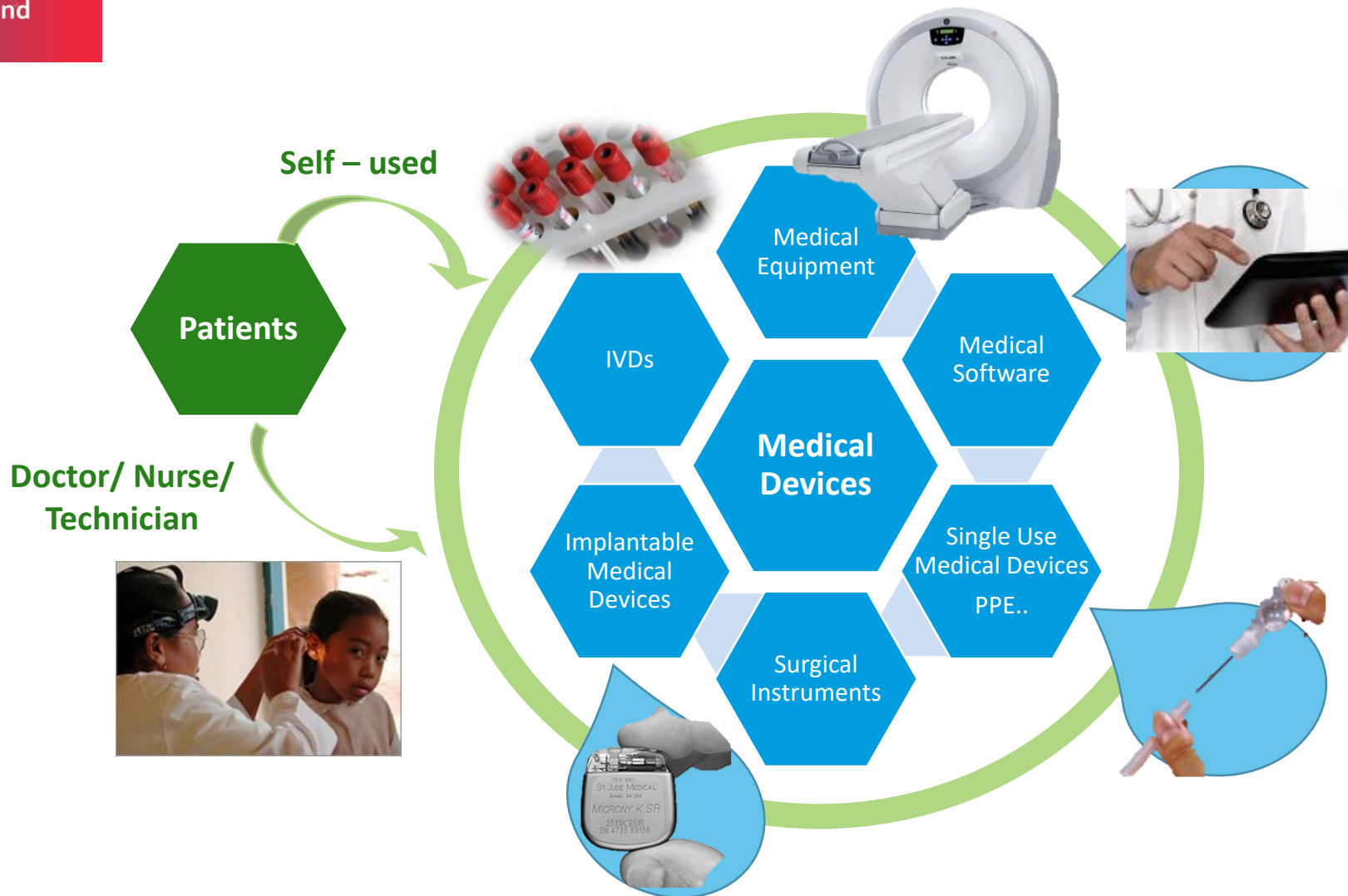
- » Regulation process of medical devices
- » Lists of approved MD for marketing in country.



- » Procurement
- » Installation, training, maintenance
- » Safe use, operating costs and clinical effectiveness
- » Post market surveillance and adverse event report
- » Decommissioning, Replacement



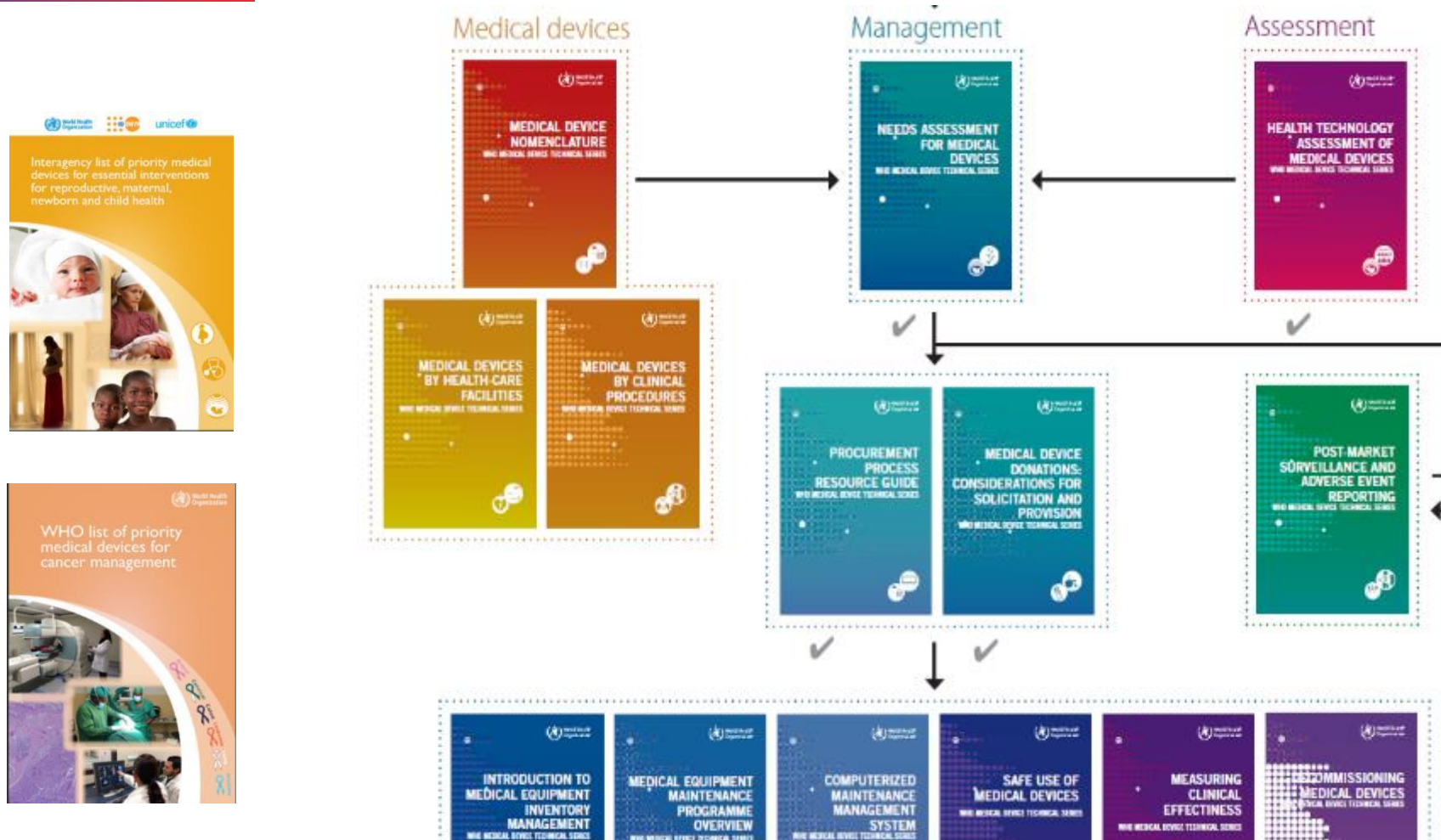
Complementary tools for Medical Devices considering:



Sequence of process to ensure access to appropriate and safe health technologies



Health technology Assessment, Health technology management and lists of priority medical devices.



WHO publishes guidance to Member States on all the topics: from innovation to post market surveillance.

https://www.who.int/health-topics/medical-devices#tab=tab_1



Innovative health technologies
(2011, 2014, 2017, 2021)



Priority medical devices for:
reproductive, maternal, newborn and
child, Cancer cardiac diseases, stroke,
diabetes (@3000 devices)
(2015, 2017, 2021*)



Essential in vitro diagnostic List (EDL)
@200 tests. (2021)



Model Regulatory Framework for
medical devices including IVDs. (2017)



guidance for Post market surveillance
(2020)



e-EDL and Priority Medical
Devices Information System
(clearinghouse) (2021*)



Procurement, donations, maintenance,
decommissioning guidance (several
publications 2011 to 2020)



Priority medical devices for COVID-19
and associated technical specifications
for procurement (2020)



Technical specifications for personal
protective equipment (2020)

https://www.who.int/health-topics/medical-devices#tab=tab_1

Regulatory systems for medical products

Harmonization, reliance, and regional sharing of information is welcome

Regulatory system strengthening for medical products WHA67.20

» URGES Member States:

- › to engage in global, regional and subregional networks of national regulatory authorities, as appropriate, recognizing the importance of collaboration to pool regulatory capacities to promote greater access to quality, safe, efficacious and affordable medical products;
- › to promote international cooperation, as appropriate, for collaboration and information sharing, including through electronic platforms;

» REQUESTS the Director-General:

- › to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health 1 And, where applicable, regional economic integration organizations. WHA67.20 5 products that are the least developed, such as regulation of medical devices, including diagnostics;
- › to promote the greater participation of Member States in existing international and regional initiatives for collaboration and cooperation in accordance with WHO principles and guidelines;

Access to medicines

https://www.who.int/health-topics/medicines#tab=tab_1



28 Mar 2016
Access to Medicines



7 Mar 2016
Amala's story: how to prevent antimicrobial resistance



26 May 2016
WHO: Pioneering methadone programme gives hope to thousands in Dar es Salaam

Commentaries



12 December 2019
All nations should have universal health care



21 April 2019
Vaccines: the powerful innovations bringing WHO life every day

Fact file

Highlight



Regulatory updates on COVID-19
Documents posted here were prepared for national regulatory authorities, regional pharmaceutical advisors, regulatory networks and associated stakeholders to provide timely information around development and regulatory approval of COVID-19 related diagnostics, treatments and vaccines.

Prequalification



World Health Organization Prequalification
The mission of WHO prequalification is to work in close cooperation with national regulatory agencies and other partner organizations to make quality priority medical products available for those who urgently need them.

News



10 February 2022 | Statement
Statement on miltefosine - Potential ocular disorders in patients treated with miltefosine...



10 February 2022 | Departmental news
WHO collaborative registration procedure using stringent regulatory authorities' medicine ...

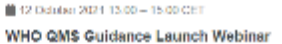


11 February 2022 | Departmental news
WHO prequalifies first monoclonal antibody - tocilizumab - to treat COVID-19



8 June 2021 | Departmental news
WHO publishes new guidance to accelerate in-country registration of WHO prequalified in vi...

Events



12 October 2021 | 13:00 – 15:00 CEST
WHO QMS Guidance Launch Webinar

WHO work on regulatory framework



It is being updated by WHO

Considering all regulatory models and networks

Reliance on other regulatory bodies, MDSAP

Including

Legal framework

Premarket, postmarket

Nomenclature, software med devices, donations, etc.

New publication to be available end 2022

Health Technology Assessment

WHA 67.23 Health interventions and technology assessment in support of UHC, (24/05/2014)

Urges member states to:

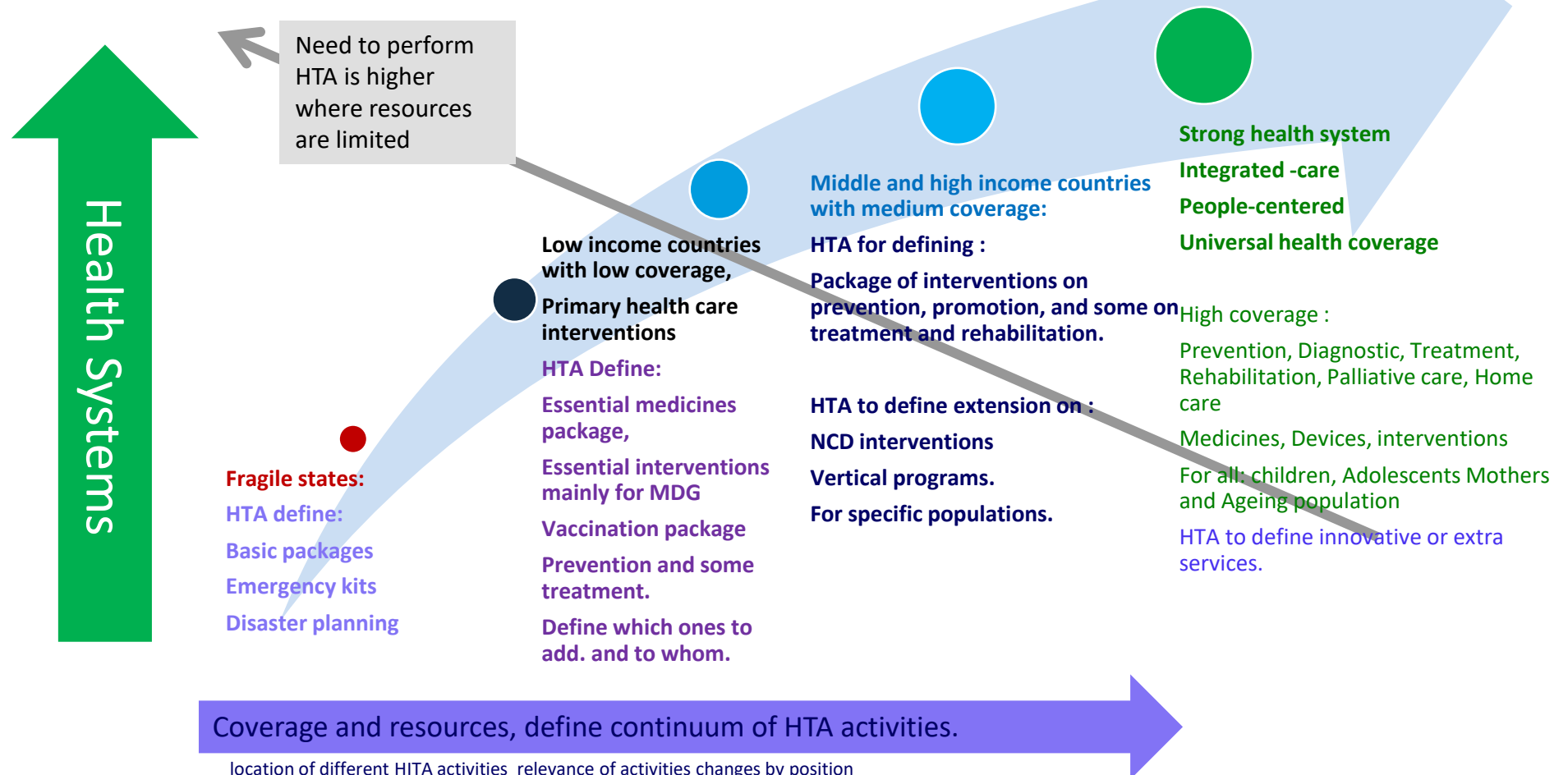
- » Establish national systems of health intervention and technology assessment to support UHC
- » To strengthen the link between HTA , HT regulations and HT management (access and use)
- » To develop national methodological and process guidelines
- » Promote HITA, for health systems strengthening and UHC...
- » To do networking and avoid duplication of efforts.
- » Collaboration with other stakeholders



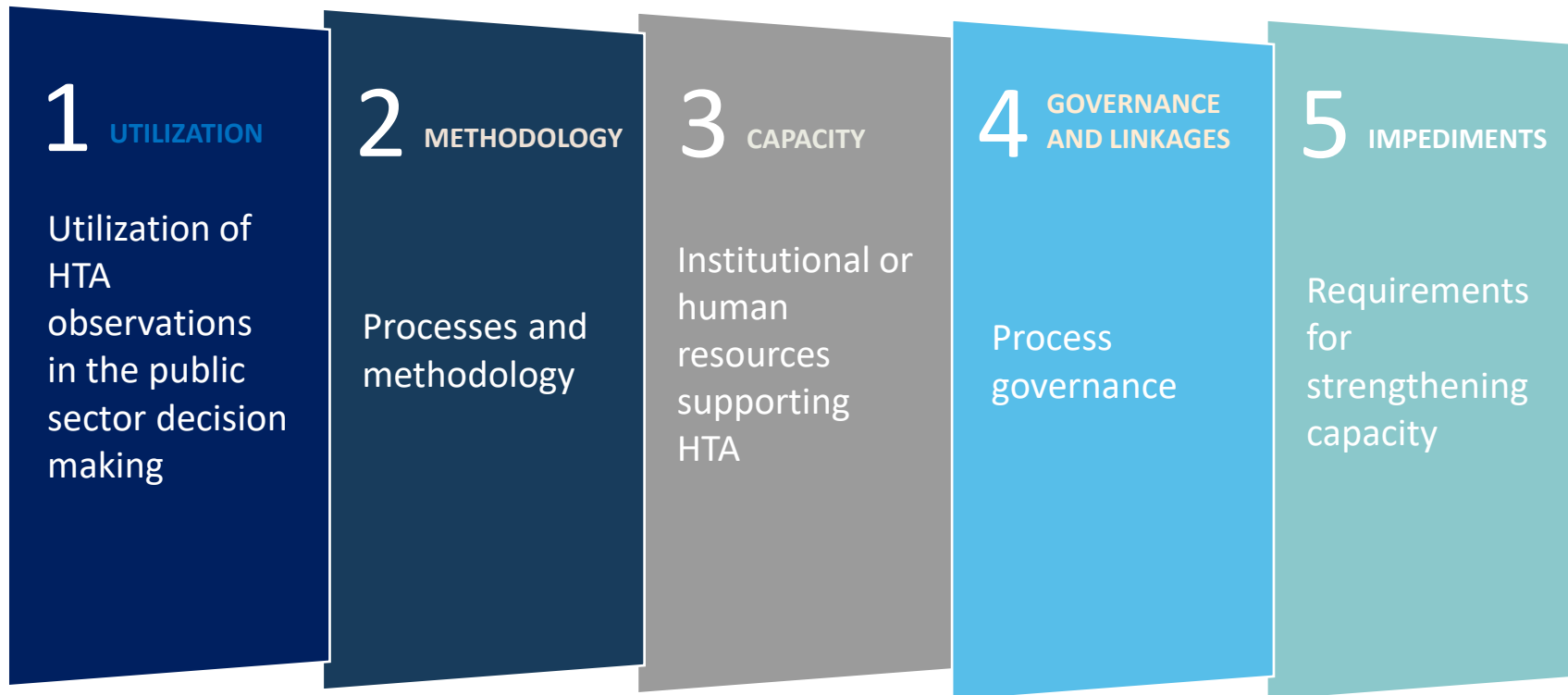
WHA 67.23 Requests the Director General of WHO:

- 1 to assess the status of HITA in member states
- 2 to raise awareness of the need for HITA
- 3 to integrate HITA concepts of HITA in WHO
- 4 provide technical support to member states
- 5 to ensure adequate capacity at all levels at WHO
- 6 To support the exchange of information and capacity building.

Continuous Spectrum of health technology assessment for priority setting and decision making by income level



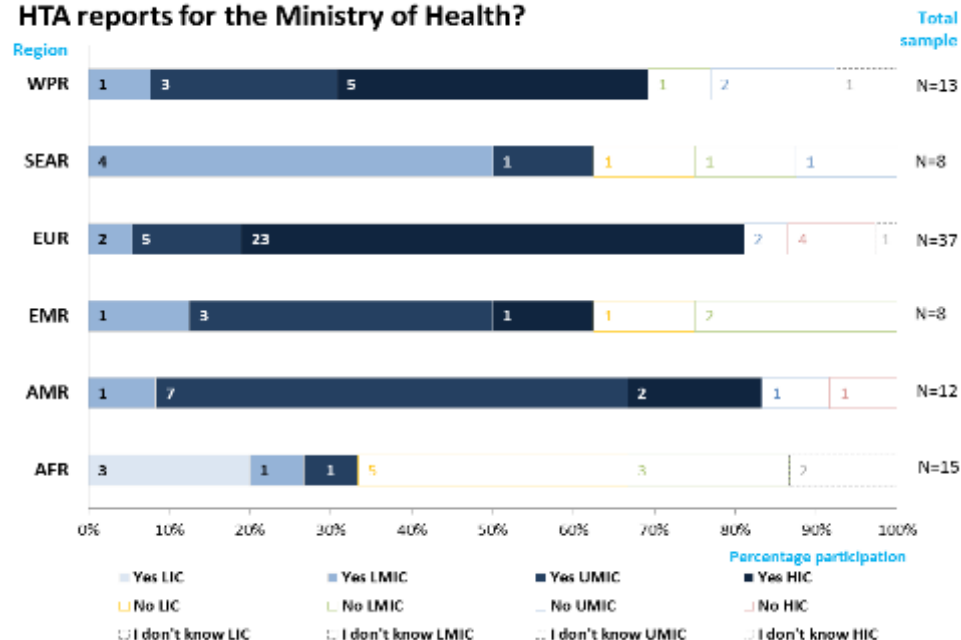
The survey had five sections matching WHA67.23 request



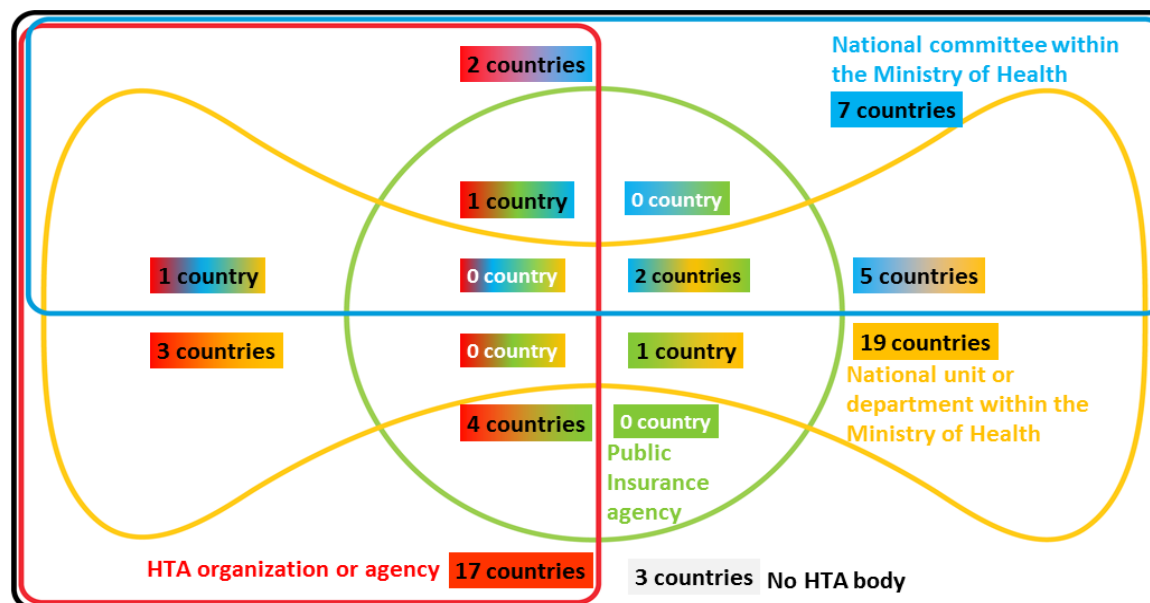
Two in three countries had a national organization that produced HTA reports for the Ministry of Health



Is there a national agency/unit/committee that produces HTA reports for the Ministry of Health?



Type of National HTA agency



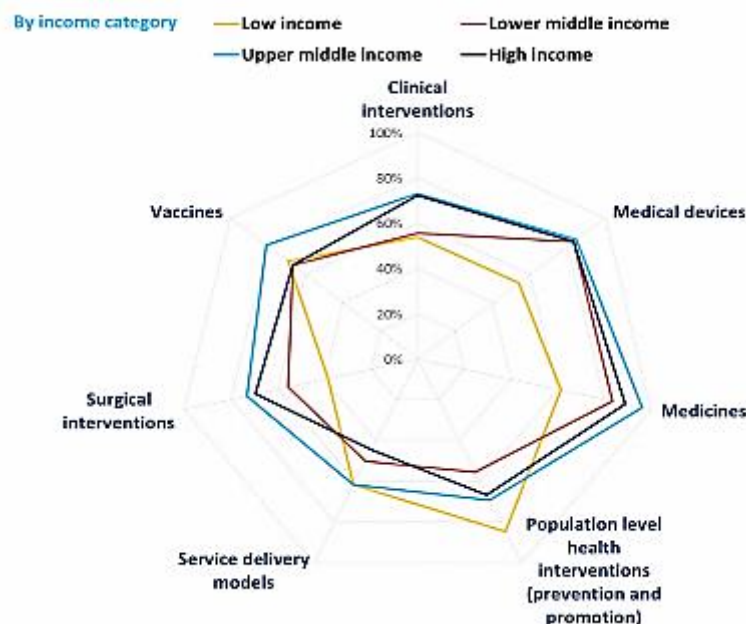
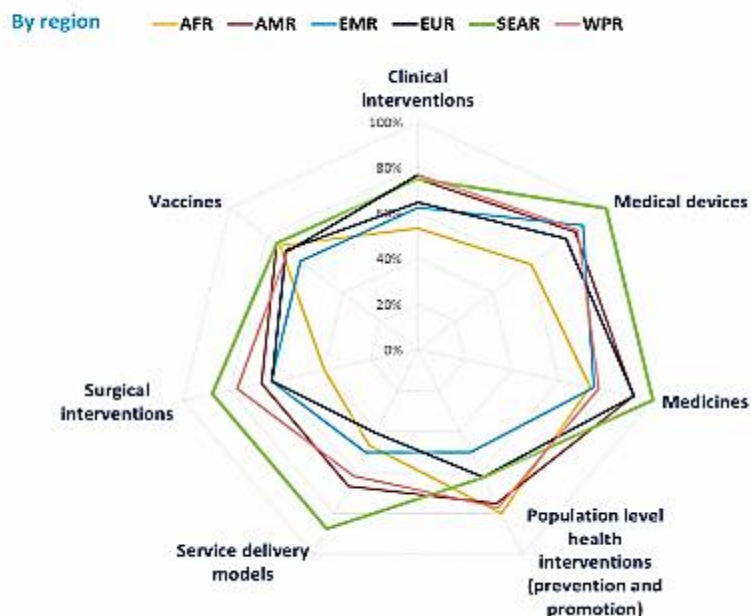
Main observations

- » Europe and the American regions had proportionally more countries with a national body that produced HTA reports for the Ministry of Health.
- » Most countries had a single HTA organisation/agency (17 countries) or a national unit or department within the Ministry of Health (19 countries) that produced HTA reports.

More than half of all respondents had considered observations of HTA in making decision for all types of health technologies and interventions

1

Select the areas where HTA is used as an element of the decision-making process



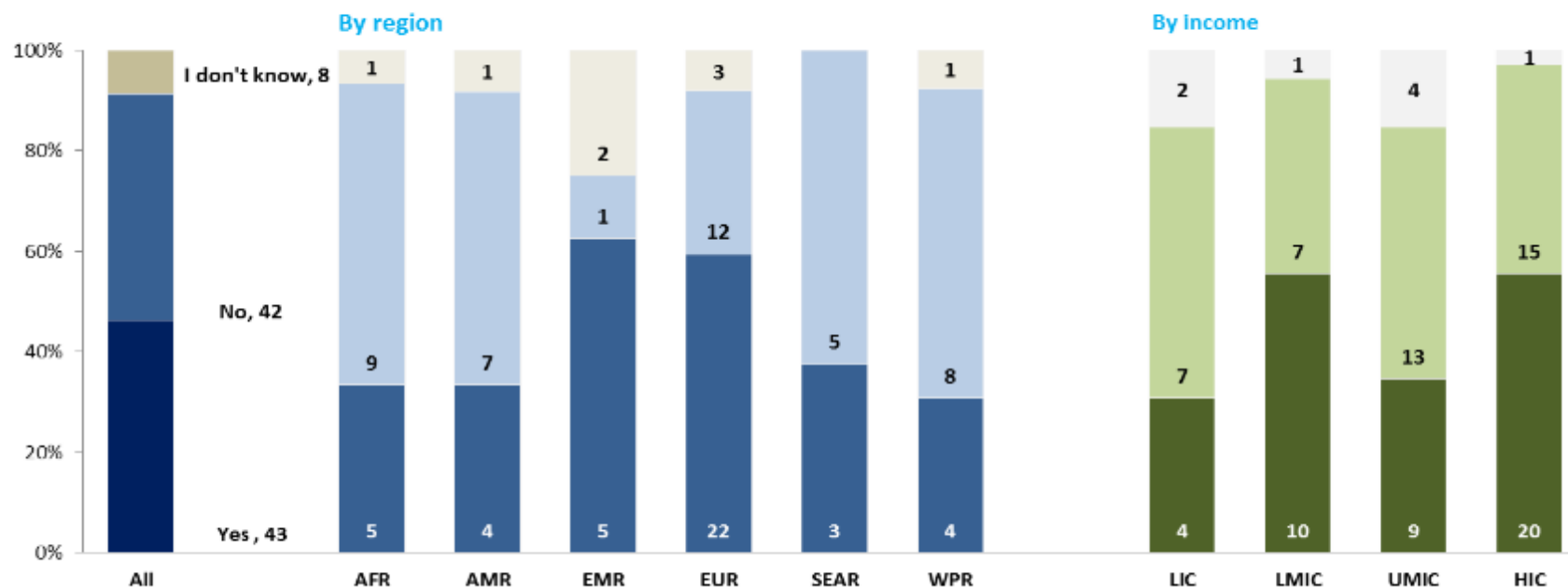
Main observations

- » More than half of the respondents used HTA across all types of health technology or intervention.
- » Proportionally more low income countries applied HTA to inform decision making for population level health interventions.
- » Proportionally less low income countries applied HTA to inform decision for medicines, medical devices and surgical interventions.

...but less than half of the countries had legislative requirements to consider the results of HTAs



Is there a legislative requirement to consider the results of HTAs in the public health decision-making process?



Main observations

- » Respondents from EMRO (63%) and EUR (63%) indicated higher level of legislative requirements to consider the results of HTAs in health care decision making than in other regions.
- » High income and low middle income countries appeared to have proportionately higher number of countries with legislative requirements.

Health technology assessment (new page in WHO)

https://www.who.int/health-topics/health-technology-assessment#tab=tab_1

Home / Health topics / Health technology assessment

Health technology assessment

Overview WHO Response Impact

New interventions and technologies are constantly being developed and tested but their impacts on health, and especially on health systems, are not always clear. Health technology assessment (HTA) is a systematic and multidisciplinary evaluation of the properties of health technologies and interventions covering both their direct and indirect consequences. It is a multidisciplinary process that aims to determine the value of a health technology and to inform guidance on how these technologies can be used in health systems around the world. HTA is a frequent and sustainable process that can be used by decision makers and other stakeholders to support the decision-making process in health care at the policy level by providing evidence on the value of health technologies. It is a process that can be used to inform the development of health policy and to support the implementation of health policy. It is a process that can be used to inform the development of health policy and to support the implementation of health policy. It is a process that can be used to inform the development of health policy and to support the implementation of health policy.

WHO Resolutions

Initiatives

Teams

Publications

Health technology assessment and evidence-based health policy
This report provides a comprehensive overview of the current state of HTA and its role in decision-making. It highlights the importance of HTA in ensuring that health technologies are safe, effective, and of good value for money. The report also discusses the challenges facing HTA and provides recommendations for how to improve the process.

Health technology assessment in the digital age
This report explores the impact of digital technologies on HTA. It discusses the opportunities and challenges of using digital data and tools for HTA. The report also provides recommendations for how to integrate digital technologies into the HTA process.

Country Profiles

Country profiles provide information on the HTA systems in different countries. They include information on the HTA process, the HTA organizations, and the HTA results. The profiles are available for a wide range of countries, including high-income, middle-income, and low-income countries.

Country profiles:

Media center Related links

Agenda

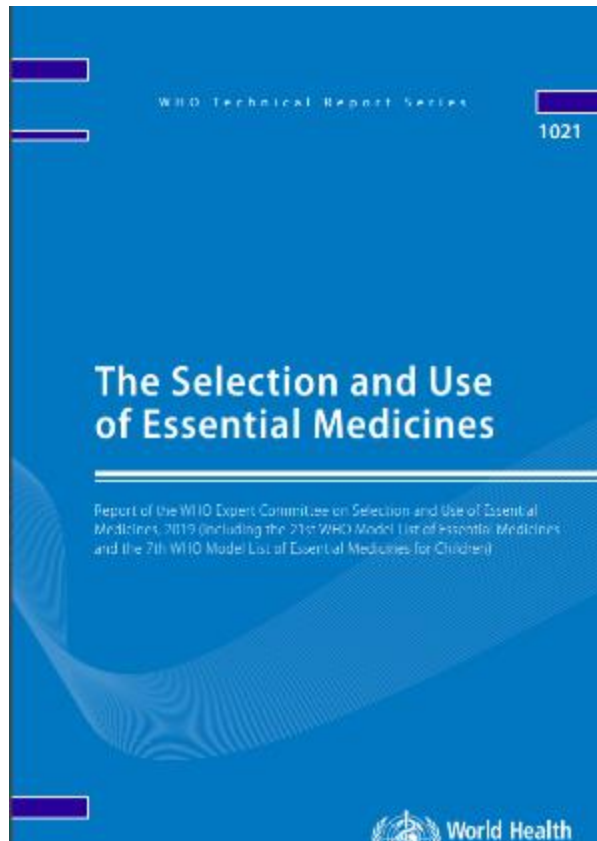
WHO ESSENTIAL AND PRIORITY LISTS

- » Medicines
- » Medical devices
- » Assistive devices
- » In vitro diagnostics

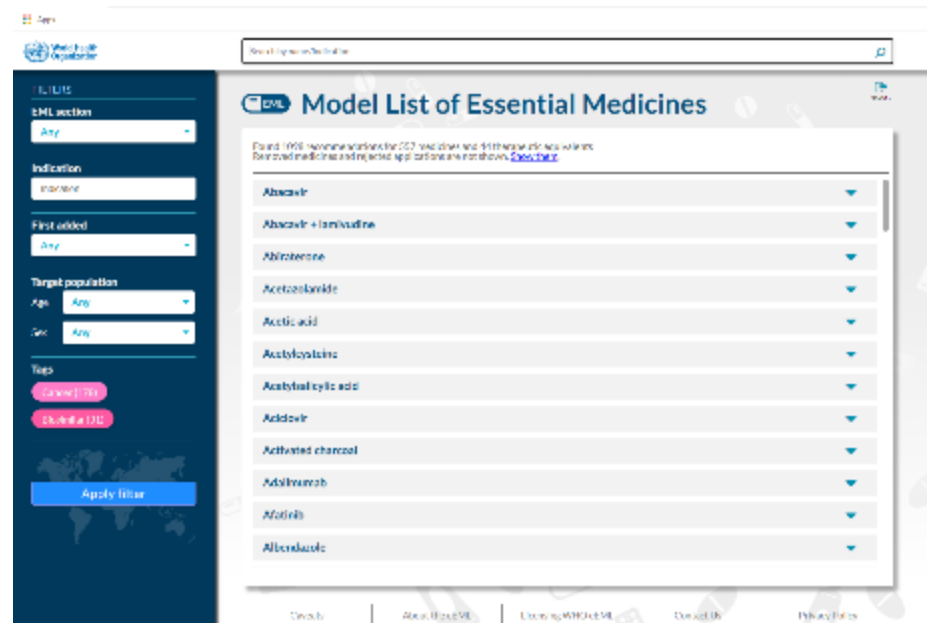
WHO Lists and process to inform development of National lists.

2022

Essential medicines List, used by many countries, include ATC, INN international codes publicly available

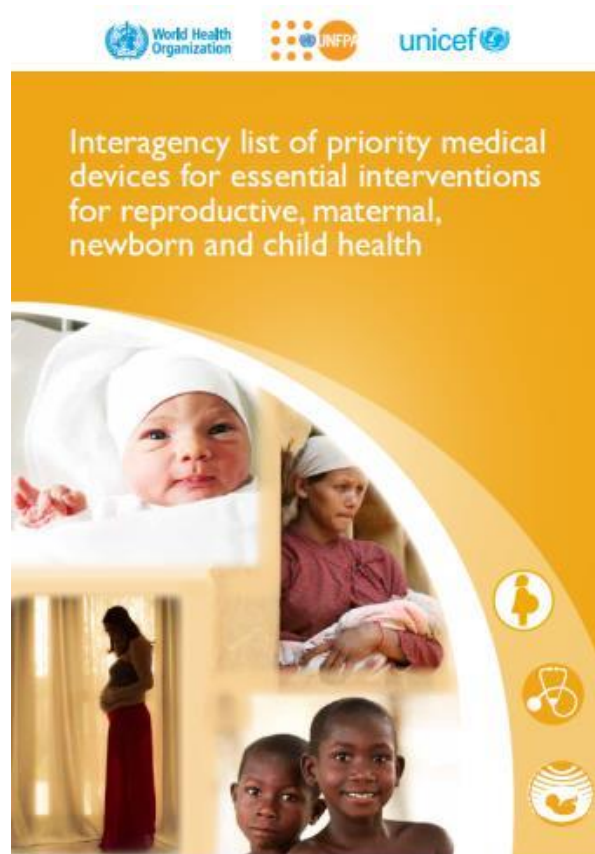


Expert committee, more 40 years ago, electronic version, selected core and complementary

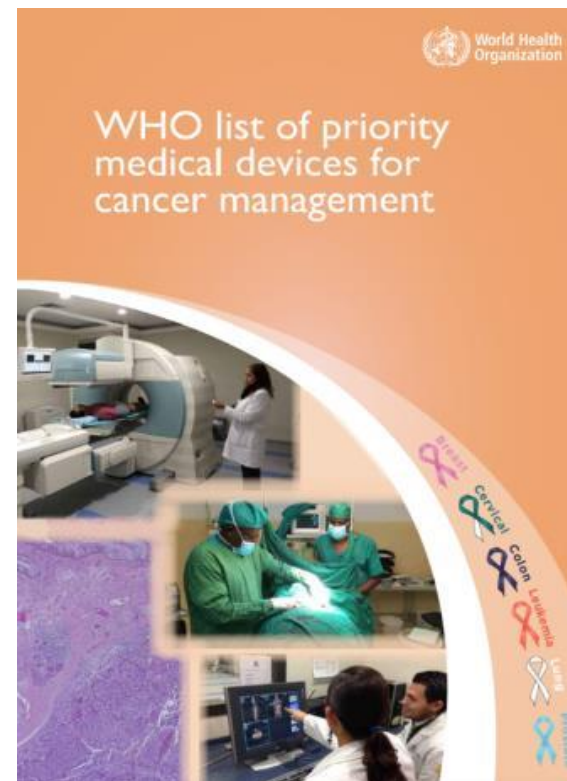


WHO Lists of Priority medical devices by interventions and levels of care (do not have internationally harmonized naming system like medicines, this hinders trade, availability, access and traceability)

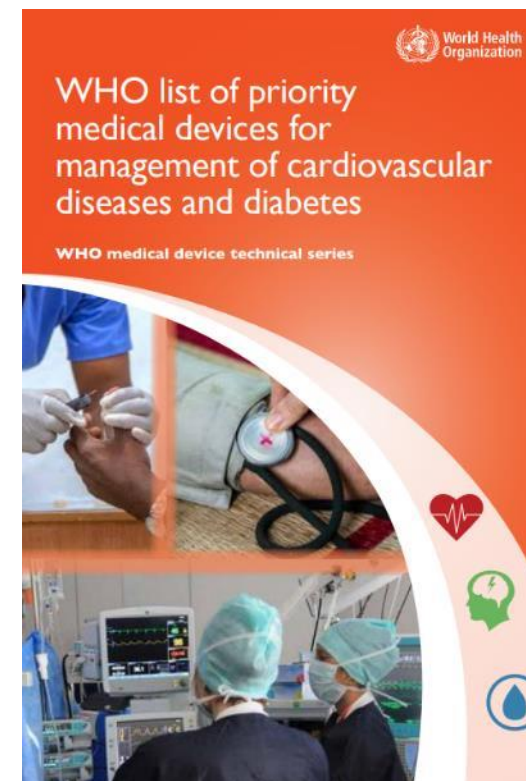
2015



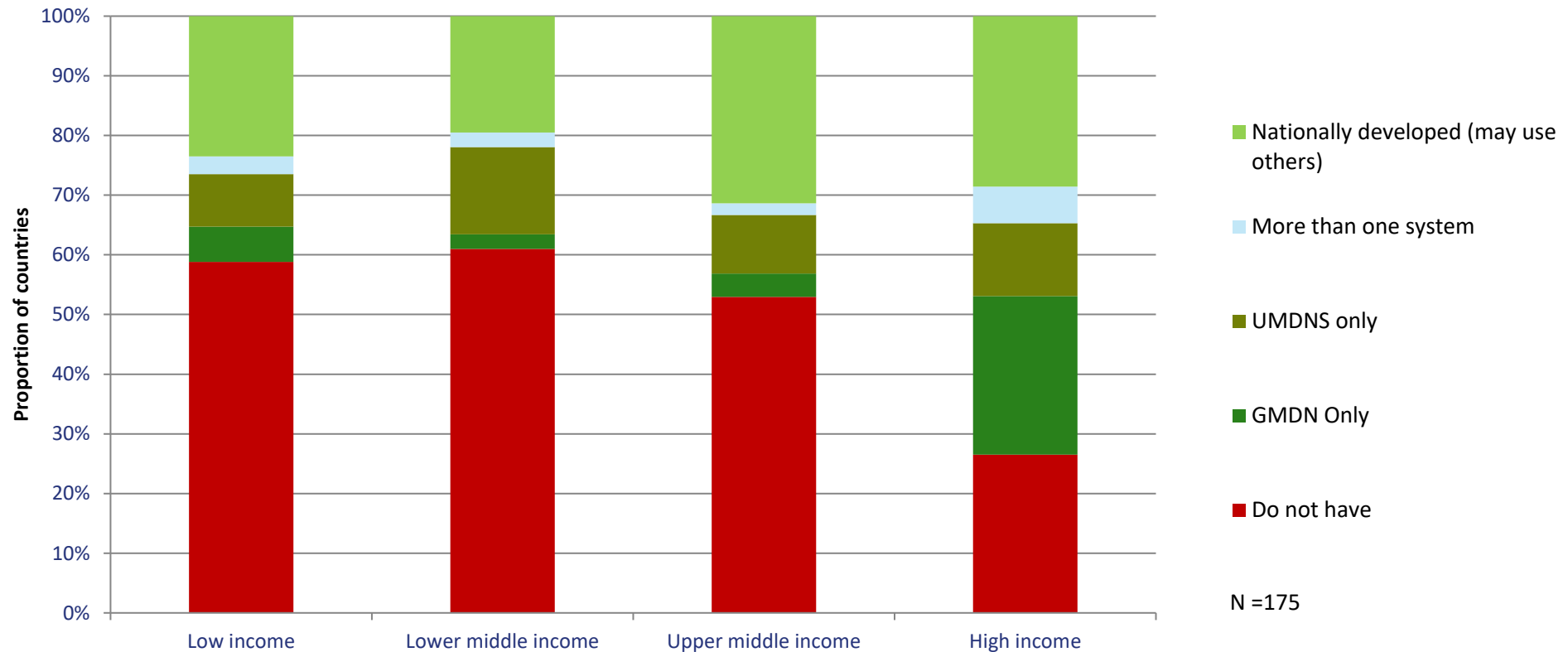
2017



2021



Country survey 2011, 2015, 2017. National nomenclature availability in countries Data in Global Atlas of Medical devices



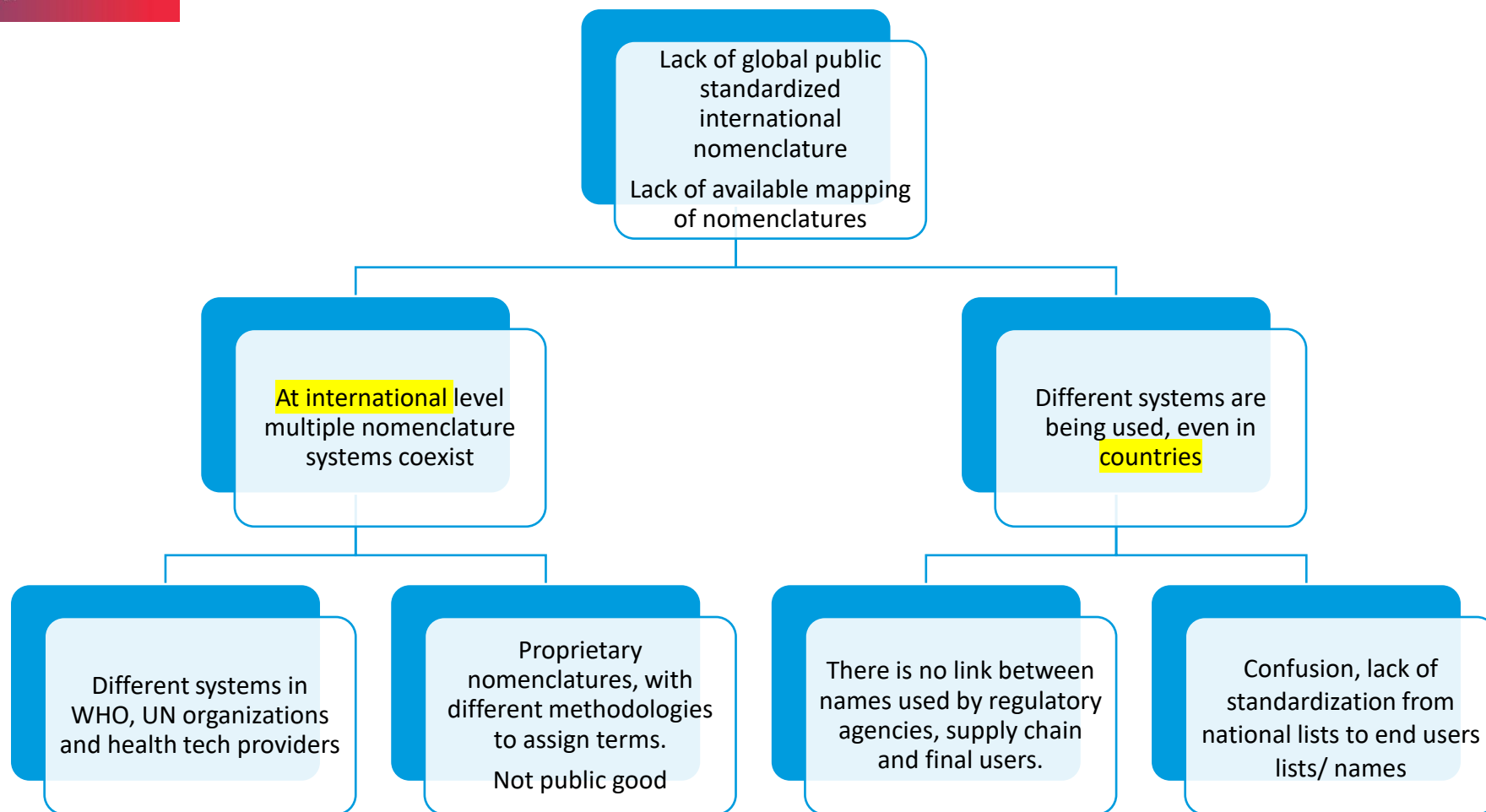
N =175

Source: WHO global atlas of medical devices, 2017
(new survey 2020 in process)

https://www.who.int/medical_devices/publications/global_atlas_meddev2017/en/

<https://icd.who.int/browse11/l-m/en>

Problems of lack of international standardized nomenclature



Priority medical devices information system MeDeViS ...

MeDeViS
Medical Devices Information System

Search by name, indication or test purpose

Browse by

- Clinical areas
- Service delivery platform
- Type of medical device
- Reusable or single use

About MEDEVIS WHO related topics Privacy policy Glossary WHO Official page

Knowledge level

- Regulatory classification
- Reusable, or single use
- Sex
- Consumable

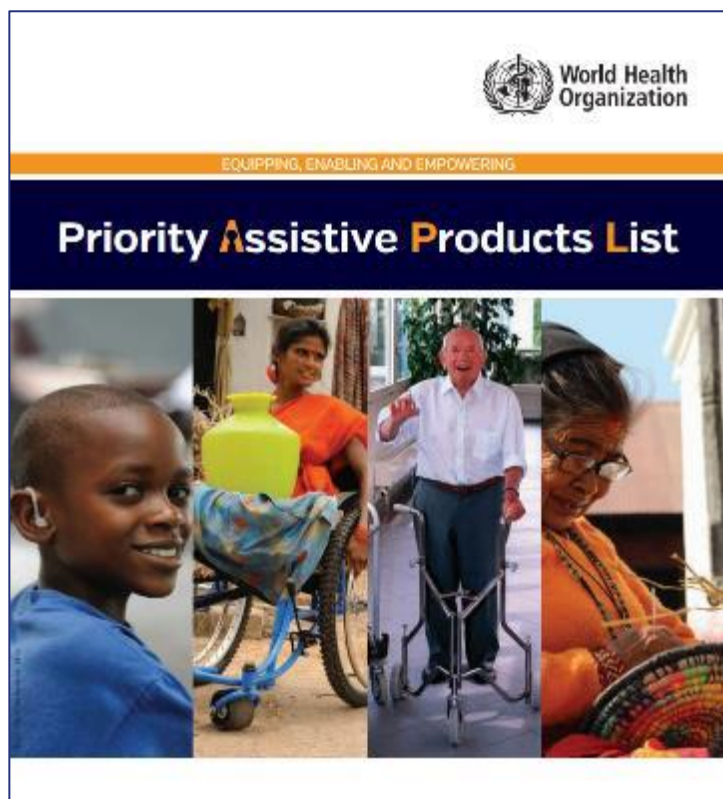
Search by name, indication or test purpose

clear

- Lancet, blood, safety, sterile (various sizes)**
CND Code: V0104 CND Nomenclature: LANCETS, SINGLE-USE
- Lancet, safety, 2.0 mm, sterile**
CND Code: V0104 CND Nomenclature: LANCETS, SINGLE-USE
- Laparoscope holder**
CND Code: -- CND Nomenclature: (Nof found)
- Laparoscopic biopsy forceps**
CND Code: K0201010602 CND Nomenclature: ELECTROSURGICAL FORCEPS, LAPAROSCOPIC, SINGLE-USE
- Laparoscopic dissection spatula**
CND Code: K0201010202 CND Nomenclature: ELECTROSURGICAL DISSECTORS, LAPAROSCOPIC, SINGLE-USE
- Laparoscopic electrosurgical blunt dissector**
CND Code: K0201010202 CND Nomenclature: ELECTROSURGICAL DISSECTORS, LAPAROSCOPIC, SINGLE-USE
- Laparoscopic grasper**
CND Code: -- CND Nomenclature: (Nof found)
- Laparoscopic grasping forceps**
CND Code: K0201010602 CND Nomenclature: ELECTROSURGICAL FORCEPS, LAPAROSCOPIC, SINGLE-USE
- Laparoscopic irrigation/aspiration cannula**
CND Code: K0201010102 CND Nomenclature: ELECTROSURGICAL MULTIFUNCTIONAL CANNULAS, LAPAROSCOPIC, SINGLE-USE
- Laparoscopic multi-instrument access port**
CND Code: -- CND Nomenclature: --
- Laparoscopic needle holder**
CND Code: L1205 CND Nomenclature: NEEDLE HOLDERS, MINI-INVASIVE SURGERY, REUSABLE

Priority assistive products (have no international name/code)

2017 50 types



Priority Assistive Products List		
1	Alarm signalers with light/sound/vibration	
2	Audioplayers with DAISY capability	
3	Braille displays (note takers)	
4	Braille writing equipment/brailers	
5	Canes/sticks	
6	Chairs for shower/bath/toilet	
7	Closed captioning displays	
8	Club foot braces	
9	Communication boards/books/cards	
10	Communication software	
11	Crutches, axillary/elbow	
12	Deafblind communicators	

WHO Essential in vitro diagnostic list: 2018, 2019, 2020 (have no international harmonized name)

Basic test characteristics

Test purpose

Test format

Specimen types

Equipment required

Regulatory status

Global availability

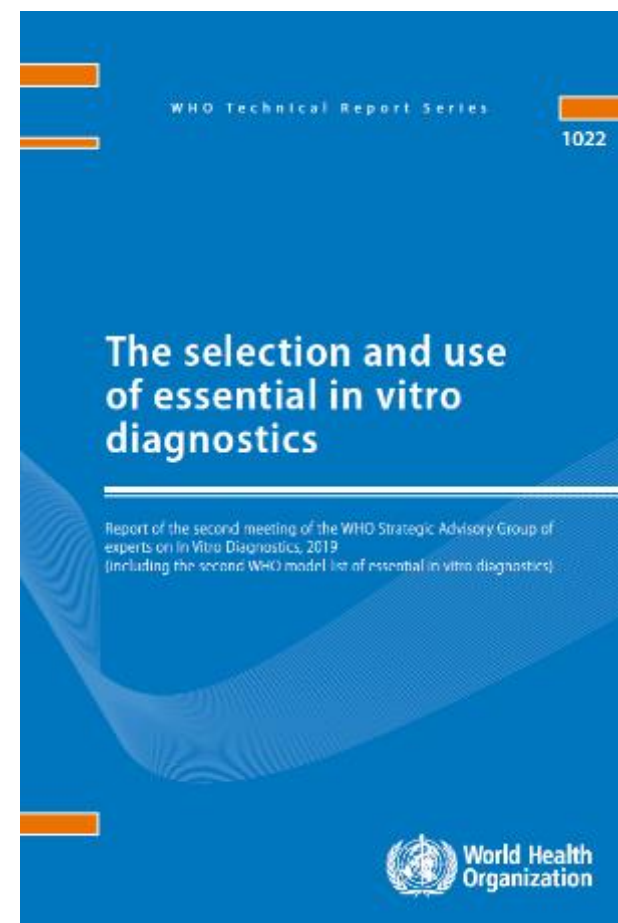
Price per test range

Instrument price range

Ethics, equity and human rights issues

Evidence for clinical usefulness and impact

Evidence for economic impact and/or cost-effectiveness



go back to list

Table of content

Details

Summary of evidence and Expert Committee
recommendations

Indication - HIV infection ICD11 code: 1C62.Z

Combined HIV antibody/p24 antigen (antiHIV/p24 Ag)

Essential In Vitro Diagnostic ✓

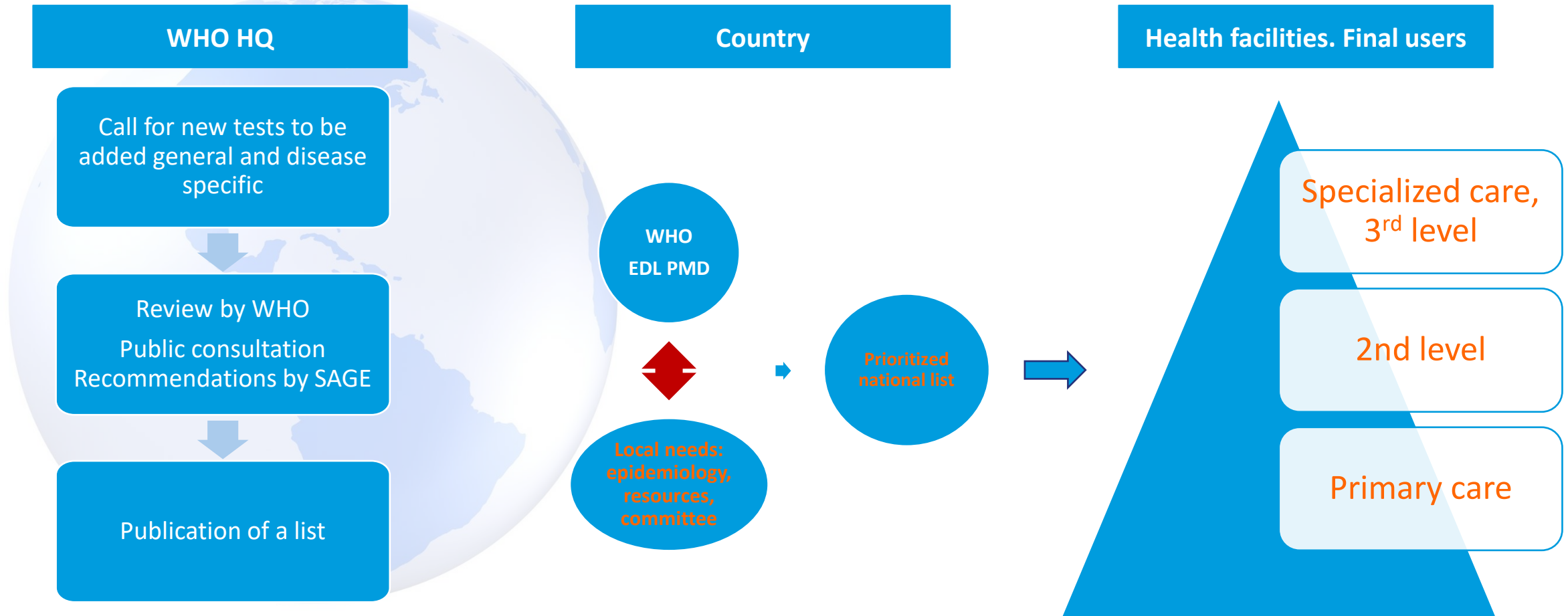
Facility level: 1. No laboratory

Assay formats	RDT
Status history	First added in 2018
Purpose type	Diagnosis
Purpose	For the diagnosis of HIV infection: adults, adolescents, children and infants > 18 months of age
Specimen types	Capillary whole blood, Venous whole blood
WHO prequalified or recommended products	Public reports of WHO prequalified IVDs http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report
WHO supporting documents	Guidelines on HIV self-testing and partner notification (2016) https://apps.who.int/iris/handle/10665/251655 ; Consolidated guidelines on HIV testing services (July 2015) https://apps.who.int/iris/handle/10665/179870 ; WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection, module 10 for testing providers (2017) http://www.who.int/hiv/pub/prep/prep-implementation-tool ; Consolidated guidelines on HIV testing services (2015) https://apps.who.int/iris/handle/10665/179870

Summary of evidence and Expert Committee recommendations

The selection of the disease specific diagnostics tests for the EDL took into account the relevant priority diseases for the WHO such as HIV infection, tuberculosis, malaria, viral hepatitis B and C, syphilis and HPV infection. For these diseases there are WHO guidelines and technical reports, including recommendations for the appropriate IVDs. These documents are the result of significant evidence review and formed the basis for the

Global Implementation: From WHO tools: EDL & PMD to **access of MD & IVDs at country level**



Conclusions

WHO role is to increase access to health products of good quality and that they become affordable and available to all that need them.

It becomes indispensable to have harmonization, reliance, international standards compliance.

WHO develops norms and standards for health products:

- » medicines, vaccines,
- » assistive and medical devices and in vitro diagnostics

Based on evidence and expert groups.

These lists should be used to support universal health coverage, emergencies and well being of local population.

Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

WHO

20, Avenue Appia
1211 Geneva

Switzerland

Email: edlsecretariat@who.int

EDL website:
http://www.who.int/medical_devices/diagnostics/Selection_in-vitro_diagnostics/en/